IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Van Rooijen *et al.*

Serial No.: 10/032,201
Conf. No.: 4943

Customer No.: 24961

Filed: December 19, 2001

For: **METHODS FOR THE PRODUCTION OF MULTIMERIC PROTEIN COMPLEXES, AND RELATED COMPOSITIONS**

Art Unit: 1638

Examiner: Fox, D. T.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"
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I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 C.F.R. §1.10 on the date indicated above and addressed to:

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Jonathan Ong

TRANSMITTAL LETTER

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Transmitted herewith are a Response to the Office Action, mailed on May 27, 2003, a Petition under 37 C.F.R. §1.53(e) and supporting documents, and a check in the amount of $240.00 for a one month extension of time (Large Entity) under 37 C.F.R. 1.17(a)(1) and for the Petition under 37 C.F.R. §1.53(e) for filing in connection with the above-referenced application.

Extension fee for response within first month by a Large Entity $110.00

Fee for Petition under 37 C.F.R. §1.53(e) $130.00

☒ The Commissioner is hereby authorized to charge this fee and any fees, including the fee for the extension of time, if the above noted amount is incorrect, that may be due in connection with this and the attached papers or with this application during its entire pendency to Deposit Account No. 50-1213 (or Deposit Account No. 08-1641). A duplicate of this sheet is enclosed.

Respectfully submitted,
HELLER EHRMAN WHITE & McAULIFFE LLP

By: _____
Stephanie Seidman
Registration No. 33,779

Attorney Docket No.: 38814-351B
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,201	12/19/2001	Gijs Van Rooijen	38814-351B	4943

24961 7590 05/27/2003

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EXAMINER	
FOX, DAVID T	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/032,201	Rooijen et al
Examiner	Group Art Unit
FOX	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -1- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 6/10/02

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-28 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☑ Claim(s) 1-28 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

The instant application was only recently forwarded to the Examiner. Upon reviewing it, the Examiner discovered that page 1 of the specification is missing. According to MPEP 601.01(d), Applicants have three options:

(A) accept the application as filed, without page 1;

(B) file omitted page 1 with an oath or declaration in compliance with 37 CFR 1.63 and 37 CFR 1.64 referring to page 1, together with a petition under 37 CFR 1.182 and the accompanying petition fee set forth in 37 CFR 1.17(h), requesting the date of submission of page 1 as the application filing date; or

(C) file a petition under 37 CFR 1.53(e) with the petition fee set forth in 37 CFR 1.17(h) alleging that page 1 was in fact deposited with the USPTO with the application papers, including any and all evidence supporting the allegation. See MPEP 503. The petition fee will be refunded if it is determined that page 1 was in fact received by the USPTO with the application papers deposited on filing.

If Applicant is willing to accept the application without page 1, an amendment of the specification is required to renumber pages of the application consecutively and to cancel any incomplete sentences caused by the absence of page 1. The amendment should be submitted in response to this Office action.

Any petition filed under part (B) or (C) above should be submitted to the Technology Center.

Accordingly, the preliminary amendment of 29 August 2002 has been entered-in-part, without entry of the portion of that amendment relating to page 1 of the specification.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4, 8, 15-16, and 20, drawn to nucleic acid molecules encoding fusion proteins comprising an oil body targeting protein and a thioredoxin-related protein comprising one or both of thioredoxin or thiroedoxin reductase, and methods for their use to transform fungal or animal cells for the production of oil bodies containing the individual protein or a multimeric protein, classified in class 435, subclass 69.8, for example.

II. Claims 3, 17-19, and 21-23, drawn to transgenic plants comprising nucleic acid molecules encoding fusion proteins comprising an oil body targeting protein and a thioredoxin-related protein, said nucleic acid molecules operably linked to seed-specific promoters, and methods for sexual crossing said plants, classified in class 800, subclass 287, for example.

III. Claim 5, drawn to an isolated fusion protein, classified in class 530, subclass 350, for example.

IV. Claims 6-7 and 9, drawn to isolated oil bodies, classified in class 554, subclass 227, for example.

V. Claims 10-11 and 26, drawn to cosmetic formulations comprising oil bodies, classified in class 424, subclass 450, for example.

VI. Claims 10, 12 and 24, drawn to a method of using oil bodies to reduce food allergenicity, and food comprising said oil bodies, classified in class 426, subclass 601, for example.

VII. Claims 13, 25 and 27, drawn to a method for using a fusion protein comprising an oil body protein and a thioredoxin-related protein as a pharmaceutical, classified in class 514, subclass 2, for example.

VIII. Claim 14, drawn to a method of immobilizing an in vitro-produced enzyme complex onto isolated oil bodies, classified in class 435, subclass 183, for example.

IX. Claim 28, drawn to a nucleic acid construct encoding an oil body protein, a protein of interest, and an oil-body-surface-avoiding linker, classified in class 536, subclass 23.4, for example.

Claim 10 will be examined to the extent that it reads on the elected invention.

The inventions are distinct, each from the other because:

Inventions I-VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The invention of Group IX requires sequences encoding an oil-body-surface-avoiding linker and a multitude of proteins of interest including hormones, antibodies, toxins, etc., each not required by the

inventions of Groups I-VIII. The inventions of Groups I-VIII require thioredoxin-related proteins and sequences encoding them, each not required by Group IX.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and different modes of operation. Group I involves methods of fungal or animal cell transformation and culture, and regulatory elements specific thereto, each not required by Group II. Group II requires methods of plant cell transformation and plant regeneration, plant-expressible regulatory elements including seed-specific promoters, and methods for sexually hybridizing plants, each not required by Group I.

Inventions I-II and IX, and Inventions III-VIII, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The isolated nucleic acid molecules and transformation methods of Groups I-II and IX are not required by the isolated proteins or isolated oil bodies and methods and compositions for their use of Groups III-VIII.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process, such as a process for cosmetically treating skin.

Inventions IV and V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a food allergen reducer and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as a method for performing enzymatic reactions in immobilized oil bodies.

Inventions VIII and each of I-VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. The method of immobilizing isolated redox fusion proteins of Group VIII is not required by any other Group, and the oil body protein/thioredoxin-related protein fusion proteins of the other Groups are not required by Group VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, classification, and fields of search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 22, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

The United States Patent and Trademark Office (USPTO) is permitting applicants to submit amendments in a revised format as set forth below. Further details of this practice are described in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, signed January 31, 2003, expected to be published in *Official Gazette* on February 25, 2003 (Notice posted on the Office's web site at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm). The revised amendment format is essentially the same as the amendment format that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. The Office plans to adopt such a revision to 37 CFR 1.121 by July of 2003, at which point compliance with revised 37 CFR 1.121 will be mandatory.

Effective immediately, **all** applicants may submit amendments in reply to Office actions using the following format. Participants in the Office's electronic file wrapper prototype[1] receiving earlier notices of the revised practice may also employ the procedures set out below.

REVISED FORMAT OF AMENDMENTS

Begin on separate sheets:
Each section of an Amendment (e.g., Claim Amendments, Specification Amendments, Drawing Amendments, and Remarks) should begin on a separate sheet. *For example*, in an amendment containing a.) introductory comments, b.) amendments to the claims, c.) amendments to the specification, and d.) remarks, each of these sections must begin on a separate sheet. This will facilitate the process of separately indexing and scanning of each part of an amendment document for placement in an electronic file wrapper.

Two versions of amended part(s) no longer required:
The current requirement in 37 CFR 1.121(b) and (c) to provide two versions (a clean version and a marked up version) f each replacement paragraph, section or claim will be waived where an amendment is submitted in revised f rmat below. The requirements for substitute specifications under 37 CFR 1.125 will be retained.

A) **Amendments to the claims:**
Each amendment document that includes a change to an existing claim, or submission of a new claim, **must include a complete listing** of all claims in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.

(1) The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. Status is indicated in a parenthetical expression following the claim number by one of the following: (original), (currently amended), (previously amended), (canceled), (withdrawn), (new), (previously added), (reinstated – formerly claim #_), (previously reinstated), (re-presented – formerly dependent claim #_), or (previously re-presented). The text of all pending claims under examination must be submitted each time any claim is amended. Canceled and withdrawn claims should be indicated by only the claim number and status.
(2) All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended" will include markings.
(3) The text of pending claims not being amended must be presented in clean version, i.e., without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version.

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[1] The Office's Electronic File Wrapper prototype program is described in *USPTO ANNOUNCES PROTOTYPE OF IMAGE PROCESSING*, 1265 *Off. Gaz. Pat. Office* 87 (Dec. 17, 2002) ("Prototype Announcement"), and applies only to Art Units 1634, 2827 and 2834.

be underlined.

(5) All of the claims in each amendment paper must be presented in ascending numerical order. Consecutive canceled or withdrawn claims may be aggregated into one statement (e.g., Claims 1 – 5 (canceled)).

Example of listing of claims (use of the word "claim" before the claim number is optional):

Claims 1-5 (canceled)

Claim 6 (withdrawn)

Claim 7 (previously amended): A bucket with a handle.

Claim 8 (currently amended): A bucket with a ~~green~~ blue handle.

Claim 9 (withdrawn)

Claim 10 (original): The bucket of claim 8 with a wooden handle.

Claim 11 (canceled)

Claim 12 (re-presented – formerly dependent claim 11) A black bucket with a wooden handle.

Claim 13 (previously added): A bucket having a circumferential upper lip.

Claim 14 (new): A bucket with plastic sides and bottom.

B) Amendments to the specification:

Amendments to the specification must be made by presenting a replacement paragraph or section marked up to show changes made relative to the immediate prior version. An accompanying clean version is not required and should not be presented. If a substitute specification is being submitted to incorporate extensive amendments, both a clean version (which will be entered) and a marked up version must be submitted as per current 37 CFR 1.125.

C) Amendments to drawing figures:

Drawing changes must be made by presenting replacement figures which incorporate the desired changes and which comply with § 1.84. An explanation of the changes made must be presented in the remarks section of the amendment. Any replacement drawing sheet must include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure or figure number of the amended drawing should **not** be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Any questions regarding the submission of amendments pursuant to the revised practice set forth in this flyer should be directed to the following legal advisors in the Office of Patent Legal Administration (OPLA): Elizabeth Dougherty (Elizabeth.Dougherty@uspto.gov), Gena Jones (Eugenia.Jones@uspto.gov) or Joe Narcavage (Joseph.Narcavage@uspto.gov). For information on the waiver or legal aspects of the prototype, please contact Jay Lucas (Jay.Lucas@uspto.gov), Senior Legal Advisor (PCTLA) or Rob Clarke (Robert.Clarke@uspto.gov), Senior Legal Advisor (OPLA). Alternatively, further information may be obtained by calling OPLA at (703) 305-1616.

* Revised Notice: See Sec. B) for changes relating to substitute specifications, and Sec. C) for changes on replacement drawing practice.

METHODS FOR THE PRODUCTION OF MULTIMERIC PROTEIN COMPLEXES, AND RELATED COMPOSITIONS

RELATED APPLICATIONS

Benefit of priority under §119(e) is claimed to U.S. provisional application Serial No. 60/302,885, filed July 5, 2001, to van Rooijen, *et al.*, entitled "METHODS FOR THE PRODUCTION OF REDOX PROTEINS". This application is a continuation-in-part of U.S. utility application Serial No. 10/006,038, filed December 4, 2001 to van Rooijen, *et al.*, entitled "METHODS FOR THE PRODUCTION OF REDOX PROTEINS", which is a continuation-in-part of U.S. utility application Serial No. 09/742,900, filed December 19, 2000 to Heifetz, *et al.*, entitled "METHOD OF PRODUCTION AND DELIVERY OF THIOREDOXIN". This application is also a continuation-in-part of U.S. utility application Serial No. 09/742,900. The subject matter of each of the provisional and utility applications is incorporated herein by reference in its entirety.

This application is related to International PCT application No. (attorney docket no. 38814-351PC), filed December 19, 2001 and Taiwanese application (attorney docket no. 38814-351TW), filed December 19, 2001. The subject matter of each of these applications is incorporated by reference in its entirety.

Field Of The Invention

The present invention relates to multimeric-protein-complexes, redox proteins, and recombinant polypeptides; and improved methods for their production.

BACKGROUND

Multimeric proteins (i.e. proteins compising multiple polypeptide chains) are a biologically and commercially important class of proteins. Antibodies for example are multimeric proteins which are used to treat a wide range of disease conditions. However in view of their complexity, multimeric proteins frequently represent significant manufacturing challenges.

THE STAMP OF THE U.S. PATENT AND TRADEMARK OFFICE AFFIXED HERETO WILL BE EVIDENCE OF RECEIPT OF THE FOLLOWING (MAILED DECEMBER 19, 2001 BY EXPRESS MAIL LABEL NO.: EL870637445US):

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ENCLOSURES: TRANSMITTAL OF UTILITY APPLICATION UNDER 37 C.F.R. §1.53 and FEE TRANSMITTAL (in duplicate); SPECIFICATION CONTAINING 146 PAGES INCLUDING CLAIMS and ABSTRACT; SEQUENCE LISTING CONTAINING 202 PAGES; COMPUTER READABLE COPY OF SEQUENCE LISTING; AND 8 SHEETS OF DRAWINGS WITH 5 FIGURES; CHECK IN THE AMOUNT OF $2,396; and RETURN POSTCARD.

APPLICANT: Gijs van Rooijen
APP. NO: TO BE ASSIGNED FILED: HEREWITH
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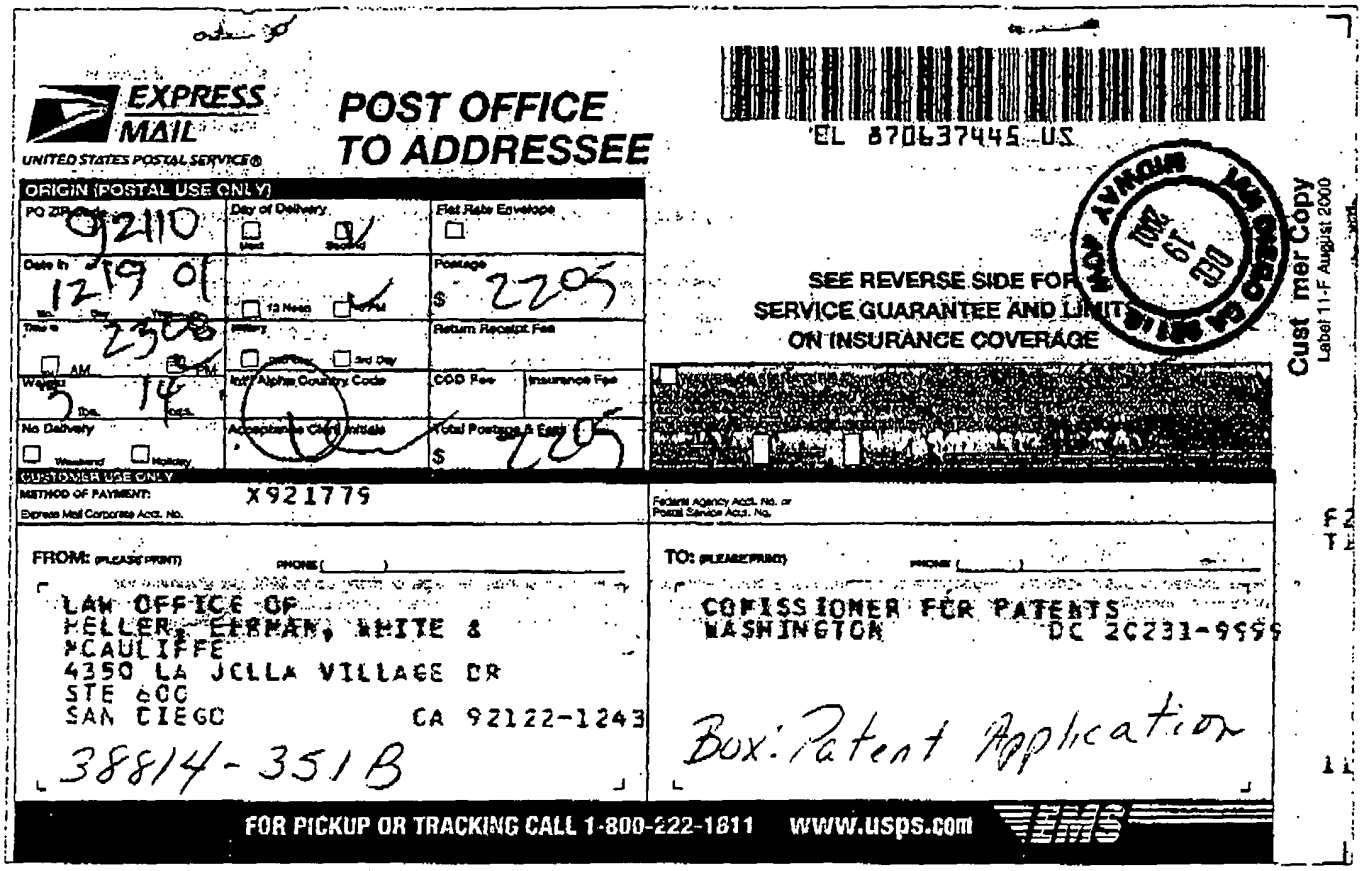

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